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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,344	03/10/2004	Bill H. McAnalley	23100.64	4291

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HAYNES AND BOONE, LLP
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EXAMINER

FLOOD, MICHELE C

ART UNIT PAPER NUMBER

1655

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/797,344	Applicant(s) MCANALLEY ET AL.	
	Examiner Michele Flood	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 1, 2 and 9-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/8/05;9/19/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on July 22, 2005, and the cancellation of Claim 4.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Election/Restriction

This application contains Claims 1, 2 and 9-31 drawn to an invention nonelected without traverse on January 21, 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 3 and 5-8 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 3, and 5-8 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide prior support or antecedent basis for the language "administering to a subject a dietary supplement comprising a nutritionally effective amount of **at least two saccharides**"; and the language "wherein prior to administration, oligomeric and polymeric forms of the at least two saccharides are predigested into a mixture of

monosaccharides and oligosaccharides" in Claim 3. Newly applied as necessitated by amendment.

The claims as set forth in the amendment filed on July 22, 2005 now recite a "A method for producing correctly structured and properly glycoproteins and/or glycolipids in a human comprising administering to a subject a dietary supplement comprising a nutritionally effective amount of at least two saccharides selected from the group consisting of galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, xylose, arabinose, glucuronic acid, galacturonic acid, iduronic acid, arabinogalactan, acetylated mannose, glucosamine and galactosamine, wherein prior to administration, oligomeric and polymeric forms of the at least two saccharides are predigested into a mixture of monosaccharides and oligosaccharides". However, the specification as originally filed provides only for a method for administering to a subject a dietary supplement comprising a nutritionally effective amount of at least one saccharide to provide the claim-designated functional effect producing correctly structured and properly glycoproteins and/or glycolipids in a human. For example, as set forth in [0029] of Patent Application Publication 2004/0171583 A1 of the present application, it is clear from the specification that Applicant intended to **include and not to exclude a method for producing correctly structure and properly functioning glycoproteins and/or glycolipids in a human comprising administering to a subject a dietary supplement comprising a nutritionally effective amount of at least one saccharide in monomeric, oligomeric or polymeric and derivatized or underivatized form**

selected from a claim-designated group of saccharides. Thus, the original concept of the invention has been narrowed to encompass a method for producing correctly structure and properly functioning glycoproteins and/or glycolipids in a human comprising administering to a subject a dietary supplement comprising a nutritionally effective amount of at least two saccharides, wherein the oligomeric or polymeric forms of the at least two saccharides are predigested into a mixture of monosaccharides and oligosaccharides without any support or evidence to support the exclusion of a method for providing the claim-designated health promoting functional effect in a human comprising the administration of a dietary supplement comprising at least one saccharide or only one saccharide, as originally filed in the as-filed specification. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim limitation is considered to be the insertion of new matter for the above reasons.

As the above-mentioned claim limitations could not be found in the present specification, the recitation of the claim limitation is deemed new matter; and, therefore it must be omitted from the claim language, unless Applicant can particularly point to the specification for literal support.

Claims 5, as amended, and Claims 6-8 is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

Claim 5 recites the limitation "the saccharides" in lines 1 to 2. There is a lack of clear antecedent basis for this limitation in the claim.

The metes and bounds of Claim 5 are rendered vague and indefinite by the phrase, "wherein the saccharides are predigested", because it is unclear as to what saccharides Applicant is referring to. Does Applicant mean that the at least two saccharides are predigested? Or, does Applicant mean that the oligomeric or polymeric forms of the at least two saccharides are predigested? The lack of clarity renders the claim ambiguous.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

Claim 3, as amended, is rejected under 35 U.S.C. 102(b) as being anticipated by Kovacs (A*). Newly applied as amended.

Applicant claims a method for producing correctly structured and properly glycoproteins and/or glycolipids in a human comprising administering to a subject a dietary supplement comprising a nutritionally effective amount of at least two

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saccharides selected from the group consisting of galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, xylose, arabinose, glucuronic acid, galacturonic acid, iduronic acid, arabinogalactan, acetylated mannose, glucosamine and galactosamine, wherein prior to administration, oligomeric and polymeric forms of the at least two saccharides are predigested into a mixture of monosaccharides and oligosaccharides.

Kovacs teaches a method of administering an effective amount of a dietary supplement comprising dehydrated mung bean sprout and beta-glucan enriched oat groat, wherein the composition comprises at least two saccharides. For instance, in Column 4, line 52 to Column 5, line 45, Kovacs teaches that the beta-glucan enriched concentrate of the oat groat contained therein the mung bean sprout and beta-glucan enriched oat groat mixture comprised glucose, xylose and mannose. Kovacs does not expressly teach the method of administering the dietary supplement as a method for producing correctly structured and properly functioning glycoproteins and/or glycolipids in a human. However, the method taught by Kovacs comprises the administration of the same ingredients instantly taught by Applicant and provides the beneficial functional effect for improving mammalian health and retarding the loss of muscle tissue in patients who are dieting and losing weight, which is indicative of improved cellular function in a human; and, thereby an indicator for the production of correctly structured and properly functioning glycoproteins and/or glycolipids, as instantly disclosed by Applicant in the present specification at [0062] and Table 4 in Column 9. Therefore, the

claimed beneficial functional effect is inherent to the method of administering the dietary supplement to humans taught by Kovacs.

The reference anticipates the claimed subject matter.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
September 30, 2005